REMARKS

The present application relates to methods for detecting a mammalian byproduct contaminant, by detecting a mammalian troponin molecule, and for distinguishing between a mammalian troponin molecule and an avian troponin molecule in animal feed. The methods include assays that employ ligands for the detection of mammalian troponin.

Claims 10-13, 15-17, and 20 are pending. Claims 10, 15, and 16 have been amended, and Claim 20 has been cancelled herein. Support for the amendments may be found in the claims as originally filed as the amendments merely delete reference to the non-elected sequences or inventions. Accordingly, no new matter is introduced by these amendments. Applicants reserve the right to pursue the cancelled subject matter in one or more divisional applications. In light of the following remarks, favorable consideration of the present application is respectfully requested.

Election/Restrictions

The Office Action maintained the objection to Claim 20 as not being directed to the elected sequence, SEQ ID NO:2. Applicants respectfully submit that the restriction requirement is inappropriate with respect to SEQ ID NOs:2-6 and 15-28, for the reasons presented in the previous response submitted March 2, 2009. That is, the sequences each share significant sequence homology, and the specification teaches that each of the sequences share specific structural features as well (*i.e.*, conserved amino acid residues that permit one to distinguish between the presence of mammalian sequences and avian sequences in a sample). However, in the interest of advancing the prosecution in this case, applicants have cancelled Claim 20 and have amended Claims 10, 15, and 16 herein to delete references to non-elected sequences or inventions. Applicants specifically reserve the right to pursue the cancelled subject matter of these claims in one or more divisional applications.

Claim rejections under 35 U.S.C. §103(a)

The Office Action maintained the rejection of Claims 10-13 and 15-17 under 35 U.S.C. §103(a), as being unpatentable over Chen *et al.*, (*Meat Science* (2002) vol. 61:55-60, available online December 21, 2001); hereinafter "Chen *et al.*") in view of Sheng *et al.* (*J. Biol. Chem.*

(1992) vol. 367(35):25407-13; hereinafter "Sheng *et al.*"). Applicants respectfully traverse this rejection.

Applicants maintain that the Patent Office has not established a *prima facie* case of obviousness in this case, and applicants have responded below to the Patent Office's arguments that were presented in the present Office Action. A *prima facie* case of obviousness requires that the following criteria must be established: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations (*See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)); (2) the Patent Office must provide an apparent reason to combine the known elements in the claims (*See KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727 (2007)); and (3) there must be a reasonable expectation of success in combining the teachings of the reference(s) (*See id.*).

Claimed Invention

The claims are drawn to assays for detecting a mammalian troponin molecule in animal feed, including the steps of extracting proteins from the animal feed to form an animal feed extract; reacting the animal feed extract with a ligand that is specific for **at least two mammalian** species troponin molecules and not specific for an **avian** troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and detecting the complex either directly or indirectly. The ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence of SEQ ID NO:2. The presence of the complex mammalian troponin molecule in the animal feed extract indicates the presence of the mammalian byproduct in the animal feed.

Prior Art Does Not Explicitly or Inherently Teach Every Claim Limitation

The Patent Office has asserted that one cannot show nonobviousness by attacking the references individually because the rejections were based on the combination of references. However, applicants note that the Patent Office must establish that the prior art references, **singly** or in **combination**, explicitly or inherently teach each and every limitation of the

claims. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Here, the Patent Office has not met this requirement.

Applicants respectfully submit that the claims are directed to **methods** of detecting mammalian troponin molecules in an animal feed extract using an antibody that recognizes a troponin molecule from **at least two mammalian** species, but not a molecule from an avian species. The Patent Office has asserted, and applicants acknowledge that Sheng *et al.* disclose SEQ ID NO:2, a rabbit skeletal muscle troponin molecule. The Patent Office also has asserted that Chen *et al.* teach the production of antibodies by immunizing mice with a skeletal muscle troponin I. Applicants note, however, that although Chen *et al.* do teach the production of a monoclonal antibody, that monoclonal antibody is **specific** for the porcine troponin I and does not detect a troponin molecule from **at least two mammalian species,** as is required by the claims. Chen *et al.*'s monoclonal antibody does not recognize troponin molecules from any other mammalian species that were tested (See page 58, second column, first full paragraph and Figures 2 and 3). Chen *et al.*'s monoclonal antibody does not even recognize all porcine troponin molecules (See page 58, second column, first full paragraph). This specificity was intentional as the authors sought to test **species authenticity** or **origin** of meats and meat products (See page 55, first column, first full paragraph and bridging paragraph). Therefore, they were interested in and described the production of antibodies that recognize a **single** species. They did not teach the production of antibodies that recognized **several** species.

Applicants' claimed methods have a very different purpose. That is, applicants have provided assays to detect any mammalian byproducts in animal feed using an antibody that can detect at least two mammalian species troponin molecules. For example, Example 1 of the present application teaches that the MT1 antibody used was able to detect "several different types of mammalian troponin I proteins including those from cow and pig" (Page 20, lines 11-12). The Patent Office has asserted that the features that applicants rely on are not recited in the claims. Applicants respectfully submit that the claims clearly require that the antibody used in the methods is "specific for a mammalian troponin molecule from **at least two mammalian species**."

The Patent Office further argued that the discovery of a previously unappreciated property or new use or function of a prior art composition does not render a claim to the old composition patentable. However, applicants note that the cited cases addressed composition claims and claims directed to processes of making compositions, as opposed to methods of using compositions as claimed here. Here, even if one were to combine the teachings of Sheng *et al.* with the teachings of Chen *et al.*, one would not arrive at the claimed invention. In fact, one would not even arrive at one component that is used in the claimed invention. As discussed above, Chen *et al.* teach the production of an antibody that is **species specific**. Therefore, if one of ordinary skill in the art were to produce an antibody according to the teaching of Chen *et al.* using the peptide disclosed by Sheng *et al.*, then they would produce a monoclonal antibody that is **species specific** to the rabbit troponin molecule.

Moreover, applicants respectfully submit that they are not even claiming a **composition** comprising an antibody that recognizes at least two mammalian species. Rather, they are claiming a **method** in which mammalian byproducts (in the form of mammalian troponin molecules) are detected in an animal feed extract, using antibodies that recognize a troponin molecule from at least two mammalian species. Neither Chen *et al.* nor Sheng *et al.* teach or remotely suggest methods for detecting mammalian byproducts in an animal feed extract. As discussed above, Chen *et al.* were trying to develop tests for **species authenticity** of heat-processed meats and meat products. Chen *et al.* did not teach or suggest methods for using the antibody for porcine troponin to detect mammalian byproducts in an animal feed extract. Sheng *et al.* simply teach the isolation and sequencing of the rabbit skeletal muscle troponin cDNA, and they do not teach or suggest methods of using the cDNA or encoded protein for detecting mammalian byproducts in an animal feed extract.

There is Not a Reasonable Expectation of Success in Arriving at the Claimed Methods

Even if the cited references did contain each of the claim limitations, there is not a reasonable expectation of success in arriving at the claimed methods if one combines the teachings of Chen *et al.* with the teachings of Sheng *et al.* First, as discussed in detail above, Chen *et al.* teach the production of a monoclonal antibody that is **specific** for the porcine troponin I. Chen *et al.*'s monoclonal antibody does not recognize troponin molecules from any

other mammalian species that were tested or even other porcine troponin molecules. This specificity was intentional as the authors sought to test **species authenticity** or **origin** of meats and meat products. By contrast, Sheng *et al.* teach that the TnI sequences from rabbit, mouse, and chicken are highly homologous at the amino acid level. Therefore, applicants respectfully submit that one of ordinary skill in the art would have been motivated to produce antibodies from the portions of the rabbit TnI protein that differed from the mouse and chicken proteins in order to produce an antibody with the desired species specificity. Such an antibody would not be useful in the claimed methods because it would identify only one potential type of mammalian byproduct.

Second, neither Chen *et al.* nor Sheng *et al.* teach or remotely suggest methods for detecting mammalian byproducts in an animal feed extract. Chen *et al.* were trying to develop tests for species authenticity of meats and meat products. Chen *et al.* do not teach or suggest methods for using the antibody for porcine troponin to detect mammalian byproducts in an animal feed extract. Sheng *et al.* also do not teach or suggest methods of using the rabbit cDNA or encoded protein for detecting mammalian byproducts in an animal feed extract. Therefore, there is no reasonable expectation at arriving at the claimed methods upon combining the teachings of Chen *et al.* and Sheng *et al.*

For at least the above reasons, applicants respectfully submit that the claims as amended are not obvious over the teachings of Chen *et al.* and Sheng *et al.* Accordingly, applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicants submit that the foregoing is a full and complete Response to the Non-Final Office Action mailed May 19, 2009. Applicants respectfully submit that the claims are in condition for allowance, and such action is courteously solicited.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 541-6662 or to Ms. Jamie Greene at (404) 745-2473 is respectfully solicited.

Applicants have submitted herewith a request for a three month extension of time, along with the appropriate fee therefore. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account Number 11-0855.

Respectfully submitted,

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